Group II:

Cy is pyrimidinyl.

Group III:

Cy is a bicyclic ring containing one nitrogen, such as benzopyrrolyl.

Group IV:

Cy is a bicyclic ring containing one or more chalcogens, such as

benzofuranyl and benzothienyl.

Group V: Cy is anything else, presumably including phenyl and naphthyl.

The applicants submit that the claims define a single invention and that the Examiner has failed to demonstrate that the claims do not relate to a single general inventive concept.

The claims share a technical relationship involving one or more of the same or corresponding special technical features that, as a whole, define a contribution over the art of record. Specifically, the Examiner has asserted that the subject matter of the Examiner's Group V is allegedly not novel over Bedell (U.S. Patent No. 6,380,258 and U.S. Patent No. 7,115,632) as the basis for asserting lack of unity of invention and requiring an election from the subject matter of the 5 Groups defined by the Examiner.

The pending claims are patentable over the cited art and consideration of the following in this regard is requested.

The Examiner is requested to make the cited patents of record by listing the same on a PTO 892 Form.

The Examiner has argued, without any specifically recited basis, that the pending claims lack novelty in view of each of US patent 6,380,258 and US Patent 7,115,632, and that this alleged lack of novelty allegedly justifies the asserted lack of unity.

In respect of U.S. Patent No. 6,380,258, the presently claimed invention is not anticipated by the patent. There is no overlap between the broadest definition in the cited patent and the presently claimed invention. The patent is understood to define the compounds by the following formula, where:

- y and z are each zero or one and the sum of z+y is one.
- X is -CH<sub>2</sub>- or -NH-.
- W is a 5- or 6-membered divalent aromatic or heteroaromatic ring.

HONH 
$$W$$
  $(X)_{2}$   $R^{3}$ 

In the claimed compounds, for example as shown below (and flipped left-to-right, for convenience):

- J<sup>1</sup> is independently a covalent bond or -C(=O)-
- J<sup>2</sup> is independently -C(=O)- or -S(=O)<sub>2</sub>-
- $\bullet$  Q<sup>2</sup> is independently: C<sub>4-8</sub>alkylene; and is optionally substituted; and has a backbone length of at least 4 atoms.
- or  $Q^2$  is independently:  $C_{5-20}$ arylene;  $C_{5-20}$ arylene- $C_{1-7}$ alkylene;  $C_{1-7}$ alkylene- $C_{5-20}$ arylene; or,  $C_{1-7}$ alkylene- $C_{5-20}$ arylene- $C_{1-7}$ alkylene; and is optionally substituted; and has a backbone length of at least 4 atoms.

$$HO-N-C - Q^2-J^2-N^4-1N-J^1-Q^1-Cy$$

First, since W must be aromatic, and since the claimed piperizine group is <u>not</u> aromatic, the piperizine group <u>must</u> be the patent's group R<sup>1</sup> if there is to be any overlap at all.

Second, if the patent's group  $R^1$  is a piperizine group, then, working back toward the acid group, the patent's group  $-S(=O)_2$ - must be  $J^2$  (as is permitted), and the patent's group  $-(CR^2R^3)_v$ -W- $(X)_z$ - must be  $Q^2$ .

Third, the patent's z must be zero, and the patent's y must be one (since  $Q^2$  does not permit an -NH- group in the chain). And so, the patent's group - $CR^2R^3$ -W- must be  $Q^2$ .

Fourth, since W is a 5- or 6-membered divalent aromatic or heteroaromatic ring, that excludes the presently claimed first option for  $Q^2$ , specifically:  $C_{4-8}$  alkylene.

Fifth, that leaves the second option of the present claims. Bearing in mind the direction, only one of the four sub-options ( $C_{5-20}$ arylene;  $C_{5-20}$ arylene- $C_{1-7}$ alkylene;  $C_{1-7}$ alkylene- $C_{5-20}$ arylene- $C_{1-7}$ alkylene- $C_{5-20}$ arylene- $C_{1-7}$ alkylene.

Sixth, the present claims also require that Q<sup>2</sup> has "a backbone length of at least 4 atoms". The patent's group -CR<sup>2</sup>R<sup>3</sup>-W- <u>can not have a backbone length of at least 4 atoms</u>. It necessarily has a backbone length of exactly 3.

Therefore, there is no overlap whatsoever between the presently claimed invention and the broadest definition in the patent. None of the examples in the patent fall within the scope of the presently claimed invention. The claims are patentable over

the cited art and the Examiner's basis for alleging lack of unity of invention is unfounded.

<u>In respect of US patent 7,115,632</u>, a similar, though simpler, analysis applies. The patent defines the compounds by the following formula, where:

• W is a 5- or 6-membered divalent aromatic or heteroaromatic ring.

$$\mathbb{R}^{20} \xrightarrow{\mathbb{Q}} \mathbb{R}^{4} \mathbb{R}^{4}$$

First, since W must be aromatic, and since the presently claimed piperizine group is <u>not</u> aromatic, the piperizine group <u>must</u> be the patent's group R<sup>1</sup> if there is to be any overlap at all.

Second, if the patent's group  $R^1$  is a piperizine group, then, working back toward the acid group, the patent's group  $-S(=O)_2$ - must be  $J^2$  (as is permitted), and the patent's group -W- must be  $Q^2$ .

Third, since W is a 5- or 6-membered divalent aromatic or heteroaromatic ring, that excludes the first option for  $Q^2$  of the presently claimed invention, specifically:  $C_{4-8}$ alkylene.

Fourth, that leaves the second option of the presently claimed invention. Only one of the four sub-options ( $C_{5-20}$ arylene;  $C_{5-20}$ arylene- $C_{1-7}$ alkylene;  $C_{1-7}$ alkylene- $C_{5-20}$ arylene- $C_{1-7}$ alkylene- $C_{5-20}$ arylene.  $C_{5-20}$ arylene.

Fifth, the present claims also require that Q<sup>2</sup> has "a backbone length of at least 4 atoms". The patent's group -W- simply can not have a backbone length of at least 4 atoms. It necessarily has a backbone length of exactly 2.

Therefore, there is no overlap whatsoever between the presently claimed invention and the broadest definition in the patent. Moreover, none of the examples in the patent fall within the scope of the presently claimed invention. The claims are patentable over the cited art and the Examiner's basis for alleging lack of unity of invention is unfounded.

Withdrawal of the lack of unity determination and restriction requirement, and examination of all of the claims, are requested.

The undersigned notes for completeness that the PTO IFW includes a copy of the Information Disclosure Statement filed January 7, 2005 with a stamp, presumably added by the USPTO, indicating that the Patent Office has allegedly not received "some FORS & NPLs". The undersigned presumes this is a suggestion that some of the cited foreign patents and non-patent literature references were allegedly not received by the Patent Office. The undersigned has reviewed the PTO IFW and confirms that a copy of each of the references listed on the PTO 1449 Forms filed January 7, 2005 are contained in the IFW. Return of an initialed copy of the PTO 1449 Forms, pursuant to MPEP § 609, is requested. The Examiner is requested to advise the undersigned, with particularity, of any cited reference which is not contained in the PTO IFW, and to allow additional time to provide a copy of same.

The undersigned notes that the Notice of Acceptance acknowledges receipt of the priority document. Acknowledgement of the same by the Examiner is also requested.

An early and favorable Action on the merits of all of the claims is requested. The Examiner is requested to contact the undersigned in the event anything further is required in this regard.

Respectfully submitted,

## **NIXON & VANDERHYE P.C.**

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